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<b>(54) Title:</b> HYPODERMIC INJECTION SYSTEM			
<b>(57) Abstract</b> <p>A hypodermic system (1) for injecting injectate from at least one injectate container (13), the system (1) having a spring-loaded carriage (57) for moving a plunger (59) through each container (13) to force injectate from the containers (13). Apparatus is provided for resetting the spring(s) (61) after completion of an injection process.</p>			

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HYPODERMIC INJECTION SYSTEMBACKGROUND OF THE INVENTIONCross Reference to Related Application

This application claims priority of U.S. Provisional Application No.60/126,062, 5 filed March 25, 1999, under Title 35, United States Code, Section 119(e).

Field of the Invention

This invention relates to hypodermic injection systems, and more particularly to injection systems wherein the injectate is held in containers, and the system discharges the injectate from the containers. The invention finds particular use as a multi-channel 10 injection system.

Description of the Prior Art

Hypodermic injection systems are widely used throughout the world today, both with respect to humans and with respect to animals. Moreover, there are many situations when multiple injections made simultaneously are either required or would be helpful. 15 Sometimes, different materials can be injected (often referred to herein as "injectates") for protecting against a variety of diseases, for serving as components for a single disease, for providing added health benefits to humans or animals, such as by way of added vitamins, minerals, etc., or to provide improved characteristics, such as to cause cattle to provide more milk, to enhance their growth, or to deliver 20 immunopharmaceutical compounds to inhibit the reproductive system in food producing animals, or a particular type of medical procedure in humans. In mass injection programs, such as injecting vast numbers of people in third world countries or large numbers of animals, a considerable amount of time could be saved if multiple injections could be made simultaneously rather than sequentially. Although there are many 25 advantages in simultaneous multiple injections, for example, in the case of young children whose vaccination schedules call for four or more injections during a single office visit, it would be a great advantage to deliver all of the vaccines in a single event to sharply limit the mental trauma that often occurs. In addition, there is the constant danger of needle sticks to the doctor, nurse or other person giving the injection, and the 30 threat of disease, such as HIV and AIDS, which should be avoided.

For injection systems which are used to give many injections, such as to large

groups of people or large numbers of animals, the system is necessarily slowed down if individual proper doses of injectate must be loaded into the injection system or if preloaded injectate containers must be manually or otherwise slowly loaded and then placed into the injection system. There is a major need for injection systems, particularly

5 multiple injection systems, which can quickly and efficiently have proper doses of the injectate loaded into the system, the injection process made, and the system reloaded quickly to continue the injection process. There is likewise a great need for the foregoing type of systems which avoids needle sticks to the person making the injection and to avoid contact with either the injectate or the injecting portion of the system by any

10 individual during or following the injection process.

#### SUMMARY OF THE INVENTION

An object of the present invention is to provide a hypodermic injection system for providing injectate from containers holding the injectate in an efficient and safe manner.

15 An object of the present invention is to provide a hypodermic injection system for avoiding needle sticks in the person administering the injection.

Another object of the present is to provide an injection system for simultaneously providing at least two injections, and further including means for preventing needle sticks to persons who are not supposed to be injected.

20 It is yet another object of the present invention to provide an injection system wherein the injectate is held in cartridges having injection orifices through which the injectate passes and enters the desired body.

It is an additional object of the present invention to provide an injection system for administering injectate from at least two cartridges.

25 Yet another object is to provide an injection system for providing injectate from at least two cartridges under jet pressure through injection orifices in each of the cartridges.

Another object of the present invention is to provide an injection system having at least two cartridges with perforators through which the injectate flows.

30 Another object of the present invention is to provide an injection system having energy storage means for energizing the system to make the injection, and a motor

operable system for re-energizing the system in a fast and economical manner.

It is yet another object of the present invention to provide a cartridge injection system having biasing means for forcing injectate from at least one cartridge into a body, where the biasing means is placed in a cocked condition by an electric motor.

5 It is a related object of the present invention to provide a motor-operated injection system wherein the electric motor is held in a handle for the injection system.

Yet still another object of the present invention is to provide an injection system having biasing means for urging injectate from a cartridge into a body, and a loading station for energizing the biasing means in a fast and economical manner.

10 Another object of the present invention is to provide a hypodermic injection system having a container holding member for holding injectate containers, the holding member with the container members being disposable after an injection without requiring any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide a hypodermic injection 15 system for simultaneously injecting injectate from at least two cartridges, the cartridges being disposable after an injection without any physical contact or handling of the disposable portion by the user.

Another object of the present invention is to provide an injection system for injecting fluid from at least one cartridge, the system having guard walls for preventing 20 splashing of the injectate during the injection process.

A further object of the present invention is to provide a hypodermic injection system for injecting injectate from at least one cartridge, the cartridge(s) being held in position by a disposable front plate.

Another object of the present invention is to provide a multi-cartridge injection 25 system with one or more springs for applying pressure to the cartridges to dispense the injectate, and a latching apparatus for cocking and releasing the spring(s).

Yet a further object of the present invention is to provide a multi-channel injection system wherein the injection means are provided in close proximity to enable multiple multi-channel injections safely and effectively.

30 Another object of the present invention is to provide an injection cartridge, the cartridge having a dispensing end with an orifice or perforator through which the

injectate can be dispensed, and a movable plunger in the cartridge which can be moved into the injectate-holding portion of the cartridge to effect the dispensing of the injectate.

An additional object of the invention is to provide an injection cartridge for holding at least two components of an injection dosage.

5 A further object of the present invention is to provide an injection system for a plurality of cartridges, the cartridges having plungers for dispensing the injection injectate in the cartridges, the injection system further having a carriage with rams for moving towards the plungers to drive the injectate from the cartridges, and means for resetting the carriage in a cocked position.

10 It is yet another object of the present invention to provide a hypodermic injection system for dispensing injectate from at least one cartridge, the system having biasing means which is placed and held in the cocked position in accordance with a sensing signal indicating whether or not a cartridge is loaded in the system.

15 It is a general object of the present invention to provide an improved hypodermic injection system which can be used for one or more injections at the same time, which is economical and fast to use with a large number of people or animals, which prevents inadvertent needle sticks, and which prevents user contact with potentially contaminated surfaces following an injection procedure..

20 Other objects and advantages will become apparent to those skilled in the art from the description to follow and from the appended claims.

The foregoing objects are achieved according to the preferred embodiment of the invention. In one preferred embodiment, a jet hypodermic injection system is provided for holding at least one cartridge for holding a serum, a vaccine or other injectate. The cartridge preferably has a dispensing end with an end portion having a channel with an 25 exit nozzle being an orifice. A plunger is provided in the cartridge, and an injectate is disposed between the plunger and the end portion. The end portion could alternatively have a perforator rather than an orifice for the exit nozzle. The system includes a housing having a disposable front end plate with holes having holding surfaces for holding the forward end of the cartridges. The housing houses a movable carriage with 30 rams for moving the plungers through the respective cartridges. The carriage is movable between a set position and a dispensing position. One or more springs move or drive the

carriage from its set position, wherein the springs are in a cocked position, to a dispensing position wherein the carriage carries the rams for moving the respective plungers through the cartridges to force injectate through the respective channels and exit nozzles into the body being injected. The spring(s) are held in a cocked position by a 5 releasable latch, which could be a solenoid piston which is actuated when a cartridge sensor emits a signal to the solenoid according to whether a cartridge or cartridges are loaded in the housing.

The carriage, in a preferred embodiment, is moved from its dispensing position to its set position, and for setting the spring(s) to their cocked condition, by a motor 10 driven cam. A cam follower extends from the carriage, and the motor rotates the cam which moves the cam follower, and hence the carriage, to the set or cocked position.

The spring(s) are preferably guided and positioned by movable rods which extend between the carriage and the rear part of the housing through which they extend. A fixed member on the rod(s) defines a shoulder for supporting one end of the spring(s); 15 the other end of the spring(s) engages the inner part of the rear wall of the housing. As the carriage moves towards the set position, it moves the respective rods and compresses the spring(s) to their cocked position.

The front plate for holding the respective cartridges is ejectable or catapulted away from the injector after the cartridges have been used, and the plate with the spent 20 cartridges are thereby disposed. This avoids the problems of needle sticks or any contact with contaminated surfaces by the doctor, nurses or other health care workers administering the injection, and also precludes unsafe and illegal use of spent cartridges.

In a preferred embodiment, the cam or other carriage resetting apparatus is moved from the final position to an initial position by means of a motor having a motor- 25 driven tool designed for rotating the cam or other apparatus. A loading station can be provided for resetting the cams of one or more injection systems according to the invention, which is preferably done when new cartridge(s) are to be loaded in the system. Alternatively, the housing can be held with a handle designed to carry the motor and possibly a power source for the motor. The system is ideally suited for injecting large 30 masses of people or animals in a safe and fast manner, providing individual or multiple injections.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a pictorial view of a hypodermic injection system of the invention showing a front end with all six injectate cartridges having orifices for the exit nozzles;

5 Figure 2 is a pictorial view of the system illustrated in Figure 1, showing the release and disposal of a used front end portion of the system;

Figure 3 is a pictorial view of the disposable front end of the preferred embodiment of the invention;

10 Figure 4 is a pictorial view of the front end of the invention showing the center two cartridges having orifices loaded in the front end and the four outer cartridge locations having dummy loads;

Figure 5 is a pictorial view of an embodiment of the invention showing the two center cartridges having perforators, and the four outer cartridge locations having dummy loads;

15 Figure 6 is a transparent pictorial view of a cartridge according to the invention;

Figure 7 is a cross-sectional view of the preferred embodiment of the energy storage part of the system shown in Figure 1;

Figure 8 is a pictorial view of another preferred embodiment of the invention showing a loading station for cocking the energy storage part of the system;

20 Figure 9 is a pictorial view of the rear portion of the embodiment shown in Figure 8; and

Figures 10-12 are schematic views of dispensing portions for a six-channel injection system according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Figures 1 and 2, a preferred embodiment of the invention is shown.

25 These figures show a hypodermic injection system 1 having a housing 3 and a handle 5. Housing 3 includes a front end or plate 7 having an injection trigger 9 and a front end release trigger 11. Trigger 9 can be in the form of a rotatable lever, whereas trigger 11 can be a depressible button. System 1 is shown for delivering six simultaneous injections as described below, although the number can be from one to N (i.e., any 30 number of injections).

Referring specifically to Figure 2, an important advantage of the present

invention is the ease of disposability of the front end with the expended cartridges to avoid inadvertent touching of the injection portion of the system and, if perforators or nozzles are used for the exit nozzles, the possibility of inadvertent needle sticks by the user. This easily precludes cross-contamination and disease from both blood and the

5 injectate on the front end of the injection system. Figure 2 shows injection system 1 following an injection. Front plate 7 is one version of a holding member for holding cartridges 13. Prior to an injection, front plate 7 holding cartridges 13 is releasably locked in housing 3 as shown in Figure 1. As explained in further detail below, the cartridges each hold a required dose of an injectate, which often is a serum or a vaccine.

10 The front part of cartridges 13 are held in front plate 7, and a rearwardly part of the cartridges are supported and held in a holding fixture 15.

After an injection has been given from the cartridges loaded in system 1, the user actuates front end trigger 11 which withdraws locking members 17 which have entered grooves 19 in front plate 7, and which further releases the springs located in the mating 15 holes at position 21 to exert a spring force urging front end 7 with cartridges 13 forwardly away from housing 3, to catapult these parts from housing 3 for disposal, such as into a container B designed to hold contaminated goods. No person or animal touches front plate 7 or cartridges 13 following the injection process and during the disposal of front plate 7.

20 Front plate 7 is shown in further detail in Figure 3. As explained earlier, front plate 7 is one of many possible devices for holding the injectate containers, such as cartridges 13. Front plate 7 includes an external front surface 23 and a rearwardly extending portion 25 into the opposite sides of which are provided grooves 19. Front plate 7 can be slid into place and grabbed by locking members 17 near the front of 25 housing 3, which are received in grooves 19, these members 17 being withdrawn upon the actuation of trigger 11. Alternatively, locking slides or the like can be removably inserted into grooves 19 to lock front plate 7 to housing 3 (of which the front end forms a part), the front plate being ejectable from the remainder of housing 3 once the locking members 17 are removed from grooves 19. Front end 7 further has holes 29 with 30 holding surfaces 31 for gripping the forward ends of cartridges 13 which are preferably press fit into holes 29 to hold the cartridges in place. The outer surfaces of cartridge 13

can have a high friction surface if necessary, to assure a firm grip. Guard rings 33 are provided around each of holes 29 in order to prevent the splashing of blood or of injectate as it flows through the exit nozzle of cartridge 13, particularly during the injection process. An additional splash ring 35 can also be provided, as shown in Figure 5 2, to add more protection against splashing.

Front plate 7 or other holding members are disposable as explained above. In order to maintain the sterility of the front end, it is provided in a package for keeping the front end sterile. Sterile packaged cartridges can be filled at the site of the injection procedure, or they can be delivered already filled with the selected vaccines ready for 10 insertion into front plate 7. Alternatively, the front end can be provided with cartridges previously inserted and filled with the proper dosage of the respective injectate to be contained therein, all of which would be provided in the sterile package of the front end in which they are being gripped. It should be noted that front end 7 could hold one cartridge, six as shown, or indeed any number of cartridges. For various practical 15 reasons as discussed below, it is anticipated that no more than six injections would be simultaneously given.

Figure 4 shows front plate 7 with six cartridges 13 loaded therein. It is not necessary that all cartridge locations contain dispensable injectate. Thus, as explained earlier, plate 7 has rearwardly extending portion 25 and opposed side grooves 19. Plate 7 20 could be slid behind removable locking members 17 which would extend into grooves 19 and would be removed when front plate 7 and cartridges 13 are ejected or catapulted from housing 3. Referring to the front portion of cartridge 13, an orifice 35 is the exit portion for the two active channels shown in Figure 4 and they extend through the forward portion of cartridge 13. The orifice is so designed that, in the preferred 25 embodiment of the invention, it defines the path for the jet flow of the injectate from cartridge 13. Orifice 35 could be replaced with a perforator, such as perforators on the order of 0.5 to 1.0 mm in length, as disclosed in U.S. patent application Serial No. 08/738,303, as shown as perforators 36 in Figure 5. The use of perforators would allow for lower injection pressures and a reduction, if not the total elimination, in the amount 30 of injectate fluid remaining on the surface following an injection. Experimental programs by the inventors have shown that perforators would sometime improve the

efficacy and also reduce impact trauma to the patient.

As explained earlier, six cartridge locations are shown. It was explained that any number of cartridges with respective injection channels could be provided. However, the protocol suggested by the Center for Disease Control (CDC) limits the number of 5 childhood injections to a maximum of four during a single visit to a health care facility. The CDC apparently feels that the number of suggested injections during an office visit might increase as more vaccines become available. The size of the patient, and the location of the injection site on the body, will limit the volume of fluid that can be realistically delivered to an injection site. This factor will no doubt be different for 10 children, adolescents and adults, for example, military personnel (who often require multiple vaccinations when entering the service or being deployed to different regions of the world).

As in Figure 4, the apparatus shown in Figure 5 need not have all cartridges containing dispensable injectate. Other cartridges, such as inactive or dummy load 15 cartridges, could be used lacking injectate at those channels. Such inactive cartridges could be coded, such as with different colors. In this case, Figure 5 shows perforators 36 at the active channels, and dummy cartridges 37 at the inactive channels.

Figure 6 shows an injectate container in its preferred form as cartridge 13. Cartridge 13 has an outer wall 38 and an inner wall 39 which defines a tube 41. Slidable 20 into tube 41 is a plunger 43 with a seal at its outer circumference to prevent leakage out the back end and which can be made from an elastomeric material, such as a rubber-like compound, plastic or even glass, but with a rubber seal. Plunger 43 is dimensioned to engage inner wall 39 in a fluid-tight manner. Plunger 43 can have two wall-engaging cylindrical portions 45 (towards the front) and 47 (towards the rear) to further discourage 25 leakage during an injection. Plunger 43 defines an injectate-holding portion 49 of cartridge 13, between plunger 43 and a forward part 51 of cartridge 13 having a channel 53 which terminates in orifice 35. The portion of cartridge 13 at its forward end has a smaller diameter than does the rearward part, and is preferably press fit into front plate 7 as explained earlier. The rear part of front plate 7 preferably engages a shoulder 55 when 30 cartridge 13 is press fit into plate 7.

Cartridge 13 could be filled on-site or could be filled off-site, depending on the

circumstances. Furthermore, cartridges 13 could be preloaded into the holding member such as front plate 7 at the site where the system is to be used, or it can be done off-site. When done off-site, the cartridge could be filled and sent to the loading facility separately from the front plate, or they could be preloaded into the front plate (or other 5 holding member) and provided in a sterile package.

Cartridges 13 could be designed for lyophilized vaccine by providing two compartments that are separated by an easily rupturable seal, such as seals 56 shown in dotted lines. One compartment would contain the lyophilized vaccine, medication or serum, and the adjoining compartment would contain the correct amount of fluid for 10 mixing it. Means could also be provided for rupturing the seal and mixing the ingredients together when a cartridge is inserted into front plate 7 or when the cartridge-laden plate is inserted into the injector. A means of mixing lyophilized vaccines in the cartridge at the time of injection is described in U.S. Patent No. 5,080,648.

Turning next to Figure 7, which is a cut-away view of system 1 without the 15 handle or triggers discussed earlier. System 1 has housing 3 and end plate 7, as explained earlier. To avoid undue complexity in Figure 7, the means for ejecting or catapulting front plate 7 away from the injector are not shown. Housing 3 houses a carriage 57 which has extending from it rams or plunger rods 59. A set of three springs 61 (for each of the three cartridges shown, there being six cartridges and springs in 20 system 1) extend around the set of drive rods 63, each of which having nuts or movable spring supports 65. Supports 65 are movable along threaded rods 63 to provide a means to adjust spring preload and, therefore, injection pressure. Housing 3 has a rear wall 67, and springs 61 have their rear ends in contact with stationary wall 67. A set of holes 69 are provided in wall 67 through which rods 63 pass and are movable. A cap or shoulder 25 71 is provided at the rear end of rod 63 for both preventing rod 63 from entering the inside chamber of housing 3 and for cooperating with a latching assembly discussed below. The latching assembly includes a solenoid 73 for each spring (however, only two are shown) and each having pistons 75 which in their energized state are inserted in front of caps 71 as part of the latching assembly. A cartridge sensor switch 79 is closed when 30 a cartridge is installed in the appropriate holding portion of housing 3, thereby retracting piston 75 away from the path of moving rod 63 and cap 71. This is illustrated in the

upper position of Figure 7.

A cam 81 rotatably mounted on a shaft or axle 83 is provided for resetting carriage assembly 57 as explained below. A cam follower 85 having follower arm 87 connected to carriage assembly 57 and a roller 89 which follows the contour of cam 81.

5 Figure 7 shows two cartridges 13 loaded in the two upper chambers 88 of the system, and no cartridge is included in bottom cartridge chamber 88. The two cartridges have plungers 43. Front plate 7 has guard rings 33 as discussed earlier.

Figure 7 shows injection system 1 after an injection has been made. Carriage 57 is in its dispensed position, having been moved all the way to the right to the front of 10 housing 3. Rams 60 have pushed plungers 43 to the forward end of cartridges 13 to discharge the injectate from the two active cartridges during the injection process. In order to reload housing 3, shaft 83 and cam 81 are rotated clockwise by a motor (as discussed below) causing roller 89 to roll across the periphery of cam 81 and move cam follower 85 and carriage 57 rearwardly to the left in Figure 7. The contour of cam 81 is 15 configured to effect this movement as its radius increases at the point of contact with roller 89. As carriage assembly 57 is moved to the left, rods 63 are forced to the left as well. Nuts 65 compress springs 61 until cam 81 has completed its rotation from an initial position to a final position, at which time springs 61 are totally compressed and rods 63 are at their leftmost or rearmost position. At this time, rams or drive rods 60 are 20 withdrawn from member 15 providing a convenient time to eject the used front end away from the injector leaving room for new cartridges having proper dosages of injectate in them, inserted into member 15. When cartridges 13 are properly installed, they again actuate switch 79, which emits a sensing signal to effect the movement of solenoid piston 75 away from the path of caps 71 on rods 63. Since no cartridge is inserted in the 25 lower channel of Figure 7, its piston 75 is extended in front of shoulder or cap 71, thus preventing that spring from contributing to the injection process.

In order to commence an injection with carriage assembly 57 in its set or cocked position and springs 61 in their cocked position as well, the user of system 1 actuates trigger 9. This action will either release a mechanical latch (not shown) or will provide a 30 slight rotation to cam 81 to allow roller 89 to release as it moves onto the sharp drop off 87 of cam 81.

5 Springs 61 drive rods 63 forwardly to move carriage assembly 57 forwardly, and thereby drive rams 60 against plungers 43 to force injectate through channels 51 of cartridges 13 and out through orifices 35 (or perforators 36). After the injection, the user actuates trigger 11, causing the catapulting of front plate 7 and cartridges 13 from the 5 unit for disposal, such as into a barrel B.

In a related embodiment, the details of which are not shown, when injection cartridges 13 are slid into the injection chamber, they could actuate a connecting rod to mechanically actuate the spring-loaded latch 75 to retract it to the non-latched position.

10 There may be situations in which housing 3 is not totally loaded with cartridges 13. In these cases, as shown in the bottom portion of Figure 7, there is no cartridge 13 in the lower chamber and the lower rod 63 has not been released from its cocked or set position. For the case where no cartridge is present when carriage 57 is first moved to the left, shoulder 71 is mechanically able to move past extended piston 75, but is not able to move past extended piston 75 when trying to move to the right unless a cartridge is 15 first inserted into the channel.

10 In the embodiment of the invention shown in Figures 1 and 2, a motor and power source are included in handle 5 for resetting cam 81 to its initial position. A unit such as that in Figures 1 and 2 is portable, easy to use, and particularly easy to use for injections for large numbers of people or large numbers of animals. Even though injector system 1 20 is small, lightweight and easy to handle, in some situations it might be advantageous to make the hypodermic injection system according to the invention even smaller and lighter, when masses of people or animals are being injected, such as where a health care worker administers hundreds or thousands of injections over the course of a day. Accordingly, the preferred embodiment shown in Figures 8 and 9 form another aspect of 25 the present invention.

Figure 8 shows two hypodermic injection systems 1 according to the invention, in this case without a handle. However, a loading station 101 is provided for putting the carriage in its set or cocked position, and for compressing or cocking the springs. Thus, housing 3 houses cam 81, springs 61, and injection chambers 88 for cartridges 13, as 30 explained earlier. Loading station 101 has a series of walls defining compartments 103, 105 and 107 for each receiving an injection system 1. Each compartment 103, 105, 107

includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 11 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive mechanism 5 stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 10 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use 15 compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be 20 done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also 25 possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also 30 apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

The injectate containers have been shown as being rigid, but in some situations flexible plastic holders might be appropriate as well.

Reference is now made to Figures 10, 11 and 12, which relate to a configuration analysis of the exit nozzles. The configuration of exit nozzles is particularly important

5 with regard to multiple simultaneous injections which are given to a limb of a small child, wherein the available surface area needed to deliver an effective injection is limited. In addition, if multiple simultaneous injections are given, it is preferable to prevent or at least minimize the overlap of injectates in the child's tissue in order to limit the possibility of an adverse reaction if the injectates should mix in the target tissue. In

10 order to achieve this non-overlap condition, the injections must be delivered a certain minimum distance apart. For this reason, the inventors have carried out a geometric analysis to determine the configuration of the exit nozzles that uses the least amount of surface area while still preventing overlap of the vaccines in the tissue. In order to make this analysis, an analysis of the volume of tissue affected by an injection was required.

15 Accordingly, a six-channel system with a delivery volume of 0.2 cc for each channel was assumed. However, it was also noted that the standard single-shot dose is actually 0.5 cc. It is possible that smaller doses from vaccine manufacturers may occur with multiple channel injections. The configurations considered by the inventors were rectangular, pentagonal with one orifice in the center, and hexagonal.

20 Pathological observation by the inventors made during the course of a U.S. Department of Agriculture study showed that the injectate spreads very little in the tissue when delivered by needle and syringe; i.e., there is a pooling effect. The research showed that a 0.2 cc needle and syringe injection occupied a spheric volume in the tissue of 0.278 cc (done empirically). When an injection is given by a jet injector, the spheric

25 volume of tissue affected is 8.79 times that of a needle and syringe (empirical). Thus, the spheric volume occupied by 0.2 cc of injectate delivered by jet injection would be 8.79 times 0.278 cc or 2.44 cc.

The diameter of a sphere D is given by dividing the volume by 0.5236 and then taking the cube root of the result. Thus, a jet injection of 0.2 cc that occupies a sphere of

30 2.44 cc would have a diameter of 1.67 cm. Using this diameter as the minimum allowable distance between each of the six exit nozzles, an analysis of the three

configurations shows that the rectangular option occupies the smallest surface area at the injection site. Based on these calculations, a six channel rectangular housing has been designed and fabricated as shown in Figures 1, 2, 3 and 4. The result of these calculations is shown in Figures 10-12, wherein Figure 9 shows a rectangular configuration, Figure 10 shows a pentagonal configuration, and Figure 11 shows a hexagonal configuration. Arrows 121 in Figure 10, 123 in Figure 11, and 125 in Figure 12 are each 1.67 cm. An arrow 127 in Figure 11 is 1.96 cm. The results of the foregoing research is shown in the following table:

Orifice Configuration and Surface Area Needed to Prevent Overlap of Six 0.2 cc Shots

<u>Orifice Configuration</u>	<u>Surface Area (cm<sup>2</sup>)</u>
Rectangle	5.58
Pentagon	6.63
Hexagon	7.24

10 The invention has been described in detail with particular emphasis on the preferred embodiments thereof, but variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains.

We claim:

1. A hypodermic injection system comprising:
  - a housing for housing at least one injectate container for an injectate to be injected from the system into a body;
  - 5 a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body; and latching and release means for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member, for disposal after the injection process.
- 10 2. A system according to claim 1 wherein said housing houses at least two injectate containers, and said disposable holding member is a structure having openings for holding each of the injectate containers.
- 15 3. A system according to claim 2 and further including guard walls around said openings for preventing splashing of the injectate or blood during an injection process.
4. A system according to claim 2 and further including splash guard walls around the outer edge of said container-holding member for preventing the splashing of the injectate during an injection process.
5. A system according to claim 2 wherein said openings are dimensioned to 20 be press fit with the injectate containers to hold the containers in place.
6. A system according to claim 1 wherein said housing has a front portion, said holding member comprises a front plate, and said latching and release means includes a groove in one of said front plate and said housing and a releasable latching member in the other of said front plate and said housing for releasably entering said 25 groove to latch said front plate to said housing.
7. A system according to claim 2 and further comprising actuatable injectate release means for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, and manually operable trigger means for actuating said injectate release means.
- 30 8. A system according to claim 7 wherein said injectate release means comprises energy storage means for storing energy to be applied to the respective

injectate containers, and wherein said trigger means actuates said storage means to cause said energy storage means to apply energy to the respective containers and transmit the injectate from the containers.

9. A system according to claim 7 wherein said energy storage means  
5 comprises at least one spring, a latch for holding the spring in a set condition, and wherein said trigger means comprises a release trigger for releasing said latch to commence the injection process.

10. A system according to claim 1 wherein said locking and release means comprises at least one locking member for cooperating with said container-holding  
10 member to lock said holding member to said housing, means for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and ejection means for ejecting said holding member and the respective containers held by said holding member from said housing.

15 11. A system according to claim 10 wherein said holding member is a plate with a peripheral edge having a groove, and wherein said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate.

12. A hypodermic injection system according to claim 1 and further  
20 including at least two injectate containers, said holding member holding said containers in proper position.

13. A system according to claim 12 wherein said injectate containers are disposable cartridges, said cartridges each including an injectate channel having injectate nozzles, and wherein said holding member comprises cartridge holders for holding said  
25 cartridges for dispensing injectate through said respective channels during the injection process.

14. A system according to claim 13 wherein at least one of said cartridges are inactive cartridges having pseudo-channels which are constructed to appear as injectate channels but are non-functional as channels, and said inactive cartridges have externally  
30 visible surfaces adjacent said pseudo-channels being coded to appear differently from corresponding surfaces of the active cartridges.

15. A system according to claim 12 wherein said injectate containers are disposable injectate cartridges, and wherein said holding member comprises cartridge-holding surfaces for holding said cartridges in position to dispense injectate, said injectate cartridges comprising:

5 an outer wall having an inner wall surface defining an inner chamber;  
a plunger engaging said inner wall surface and being movable in said chamber, said plunger defining an injectate-holding portion of said chamber and said chamber having an injectate dispensing end having an exit nozzle, said dispensing end being configured to engage the respective cartridge-holding surfaces, said plunger being  
10 drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process.

16. A system according to claim 15 wherein said injectate-holding portion of at least one of said cartridges comprising a rupturable seal dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an  
15 injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate.

17. A system according to claim 16 and further including means for rupturing said seal.

18. A system according to claim 1 and further including biasing means for  
20 placing sufficient pressure on said respective containers to force the injectate out of the containers at jet velocity.

19. A system according to claim 12 wherein said injectate containers are six cartridges having injectate exits, said exits being disposed in a rectangular order having three pairs of opposing exits.

25 20. A system according to claim 12 wherein said injectate containers are cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process.

21. A system according to claim 1 wherein said housing houses an injectate container, and said disposable holding member is a structure having openings for holding  
30 said injectate container.

22. A system according to claim 21 and further including a guard wall around

said opening for preventing splashing of the injectate or blood during an injection process.

23. A hypodermic injection system for dispensing injectate from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit 5 nozzle, and a plunger for moving through the cartridge to dispense injectate from the cartridge, said system comprising:

a holding member for holding the respective injectate cartridges with said dispensing channels directed in a common direction;

10 ram means movable with respect to each of said cartridges to move the respective plungers for forcing injectate from the cartridges through the dispensing channels and the exit nozzle;

a carriage movable from a set position to a dispensing position for moving said ram means at uniform pressures during an injection process;

15 spring means movable from a cocked position for moving said carriage from the set position to the dispensing position;

carriage resetting means for moving said carriage from the dispensing position to the set position, and for recocking said spring means, to enable the replacement of the injectate containers; and

20 releasable latching means for latching said spring means in the cocked position.

24. A system according to claim 23 and further including a housing for housing said holding member, said ram means, said carriage, said spring means, said latching means, said carriage resetting means and said releasable latching means.

25. A system according to claim 24 and further comprising:

25 a guard plate near said exit orifices for preventing the splashing of injectate from said channels.

26. A system according to claim 23 wherein said carriage resetting means comprises a cam follower operatively connected to said carriage and a cam configured for moving said cam follower and said carriage from the dispensing position to the set 30 position.

27. A system according to claim 23 and further including a housing having a

fixed wall for said spring mean, and wherein said spring means comprises at least one spring having one end engaged with said fixed wall, and the other end movable to the cocked position when said carriage moves to the set position, said set of springs moving said carriage from the set position to the dispensing position in response to release of 5 said latching means.

28. A system according to claim 27 wherein said spring means further includes movable rods associated with the respective springs for guiding and positioning said springs, said rods having a wall for engaging the other end of the respective springs and being movable in response to movement of said carriage from the dispensing 10 position to the set position for moving said respective springs to the cocked position and wherein said latching means comprises a first latching member extending from said housing and a second latching member on said rods, said first and second latching members having one condition for holding said rods and said respective springs in the cocked position and a second condition for releasing said rods and said respective 15 springs, said respective springs then moving said carriage assembly to the dispensing position.

29. A system according to claim 23 wherein said carriage assembly resetting means comprises a cam follower operatively connected to said carriage and a cam movable from an initial position to a final position and configured for moving said cam 20 follower to move said carriage from the dispensing position to the set position, and a trigger for moving said cam from the final position to the initial position and for releasing said latching means to release said latching means to effect the movement of said spring means from the cocked position to move said carriage from the set position to the dispensing position.

25 30. A system according to claim 28 and further including a solenoid responsive to sensing signals for releasing said first latching member to unlatch said spring means.

31. A system according to claim 23 wherein said carriage resetting means comprises a carriage resetting apparatus for being operable for moving said carriage from 30 the dispensing position to the set position, and a drive apparatus movable for operating said resetting apparatus, said drive apparatus being configured to be moved by a

correspondingly configured motor driven device.

32. A system according to claim 31 wherein said carriage resetting apparatus is a cam follower for moving said carriage from the dispensing position to the set position, and said drive apparatus is a cam operatively connected to said cam follower,  
5 said cam being rotatable by a motor and configured to move said cam follower and said carriage from the dispensing condition to the set position, and said latching means latching said spring means in the cocked position in response to movement of said carriage to the set position.

33. A system according to claim 31 and further including:  
10 a housing for housing said holding member, said ram means, said carriage assembly, said spring means, said carriage assembly resetting apparatus, said drive apparatus and said releasable latching means; and

said system further comprising a handle attached to said housing, said handle including:

15 a motor;  
a movable tool driven by said motor for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position; and

a power input apparatus for supplying electric power to said motor.

20 34. A system according to claim 31 and further including:  
a housing for housing said holding member, said ram means, said carriage, said spring means, said carriage resetting apparatus, said drive apparatus and said releasable latching means; and

25 a loading station for cooperating with said housing to operate said carriage resetting apparatus, said loading station including a motor and a movable tool for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position.

35. A system according to claim 23 and further including sensing means for emitting a sensing signal to indicate the presence or absence of at least one cartridge held  
30 by said holding member, and wherein said releasable latching means operates in response to the presence or absence of the sensing signal.

36. A station for re-energizing a hypodermic injection system, the injection system having a mechanical energy storing apparatus for releasing stored energy when the system makes an injection, the mechanical energy storing apparatus having an input mechanism for cooperating with a re-energizing mechanism, said station comprising:

5 an energy transferring apparatus for transferring energy from an energy source;

a re-energizing mechanism for transmitting energy from said energy transferring apparatus to the input mechanism of the energy storing apparatus, said re-energizing mechanism cooperating with the input mechanism to effect the transmission  
10 of energy from said energy transferring apparatus to the mechanical energy storing apparatus.

37. A station according to claim 1 wherein the injection system has a predetermined external configuration and the input mechanism has a drivable surface for receiving energy to be stored in the energy storing apparatus, and wherein said re-energizing apparatus has a drive surface for cooperating with the drivable surface to re-energize the energy storing apparatus of the injection system.

38. A station according to claim 37 wherein the input mechanism comprising a cam mounted on an axle and the drivable surface is a surface of the axle, and wherein said drive surface of said re-energizing apparatus is a device for contacting the drivable  
20 surface and rotating the axle to rotate the cam.

39. A station according to claim 37 wherein the injection system has a predetermined external configuration, and said station includes at least one nesting apparatus for receiving and supporting the injection system, and wherein said drive surface cooperates with the drivable surface of the injection system to re-energize the  
25 energy storing apparatus of the system.

40. A system according to claim 39 wherein the energy storing apparatus of the injection system is at least one spring, and said re-energizing mechanism cocks the spring.

41. A station according to claim 40 wherein the injection system further  
30 includes a rotatable cam for operating a device to cock the spring and the drivable surface is connected to the cam, and wherein said drive surface cooperates with the

drivable surface to rotate the cam and cock the spring.

42. A station according to claim 39 wherein the injection system includes apparatus for receiving disposable cartridges holding injectate, and wherein said station further including a supporting device to hold the injection system for reloading the 5 injection system with fresh cartridges containing injectate.

43. A station according to claim 36 wherein said re-energizing mechanism includes a manually operable member for transmitting energy from a person operating said member to the mechanical energy storing apparatus.

44. A station according to claim 36 wherein said re-energizing mechanism 10 includes a compressed gas operable member for transmitting energy from the compressed gas to the mechanical energy storing apparatus.

45. A station according to claim 36 wherein said re-energizing mechanism includes an hydraulically operable member for transmitting energy from the device exerting pressure on the hydraulic fluid to the mechanical energy storing apparatus.

15 46. A station according to claim 36 wherein said re-energizing mechanism includes an ignitable gas operable member for transmitting the ignition energy to the mechanical energy storing apparatus.

47. A station according to claim 36 wherein said re-energizing mechanism 20 includes an electrically operable member for transmitting electrical energy to the mechanical energy storing apparatus.

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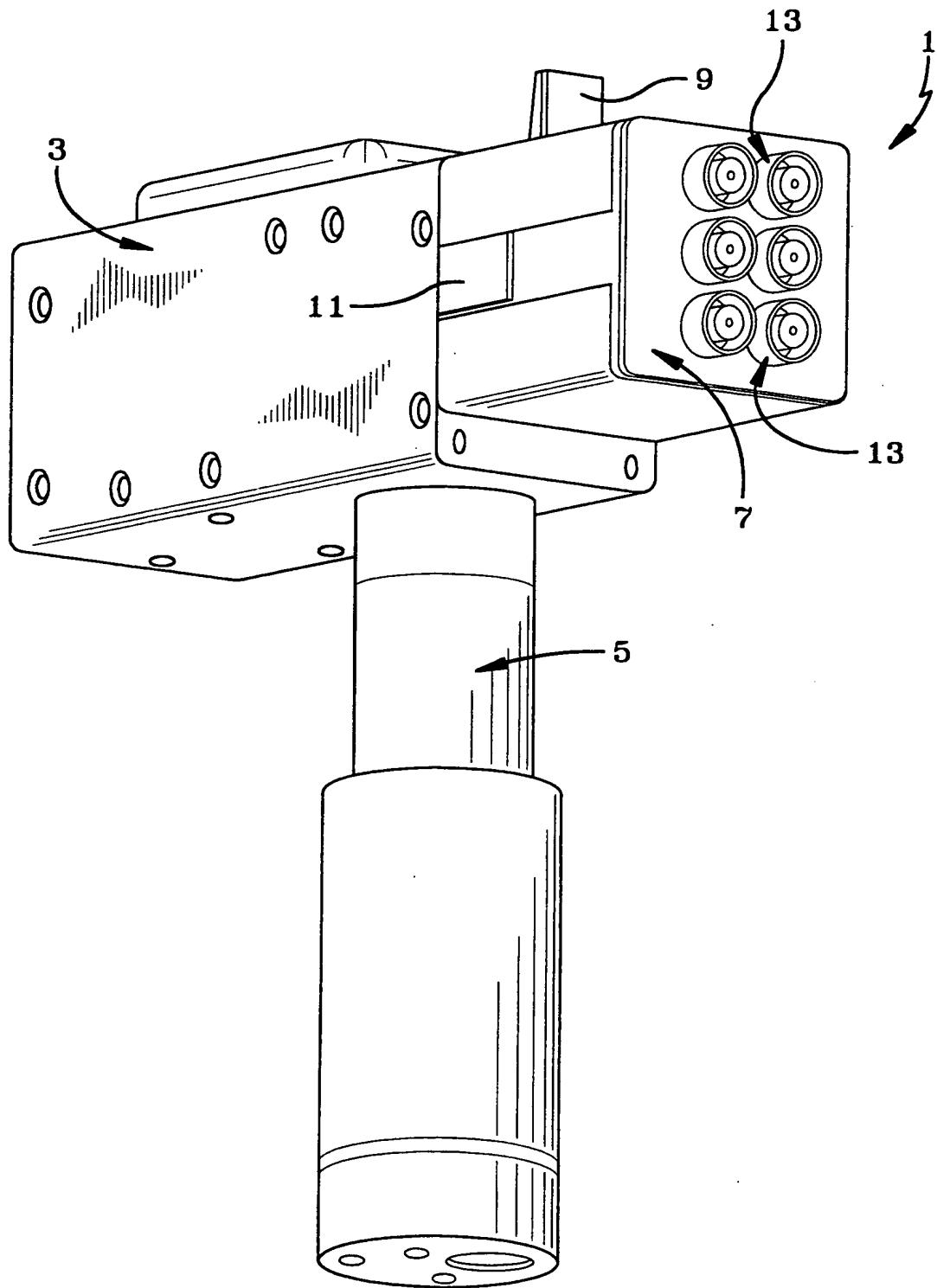


FIG-1

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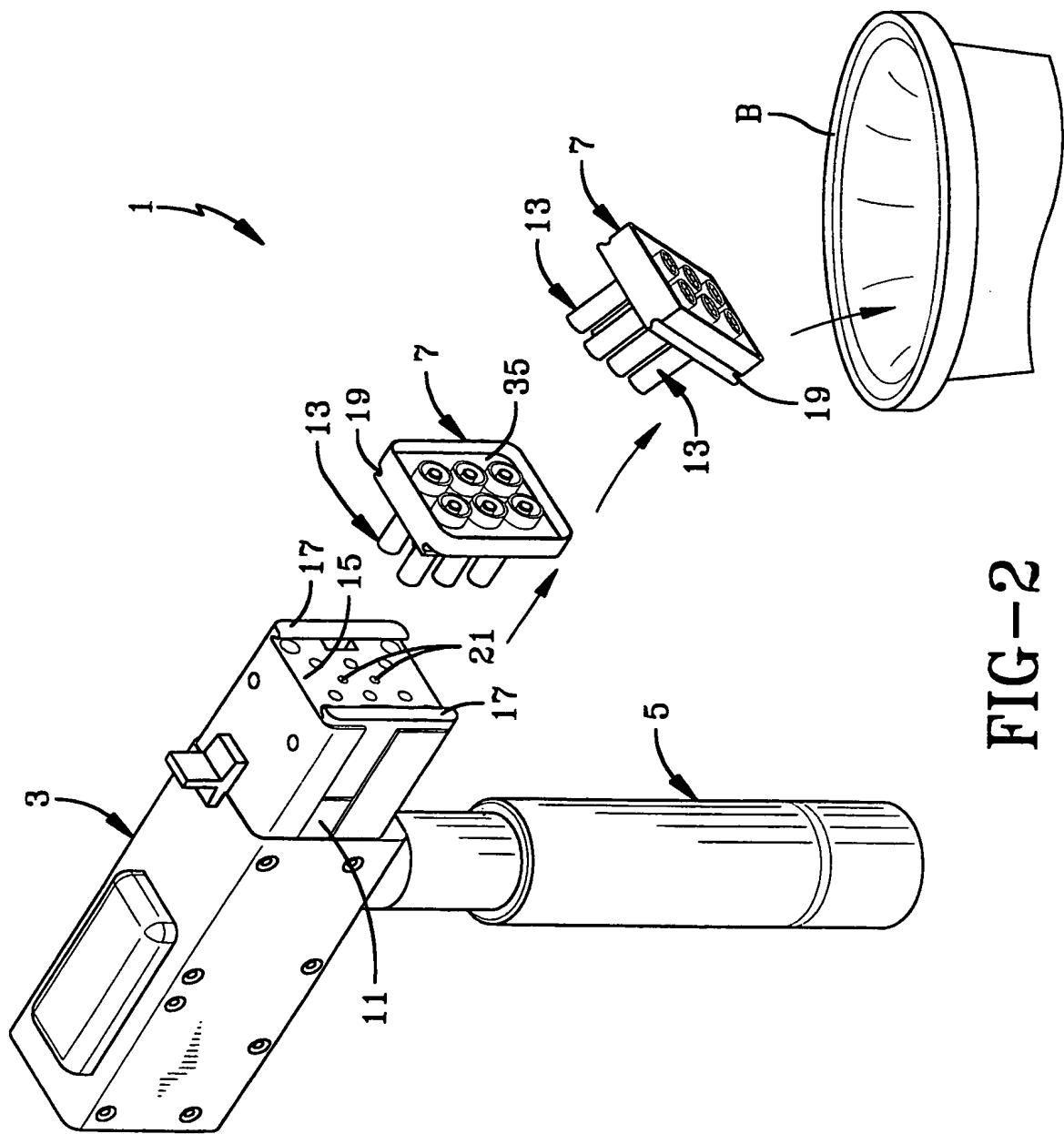


FIG-2

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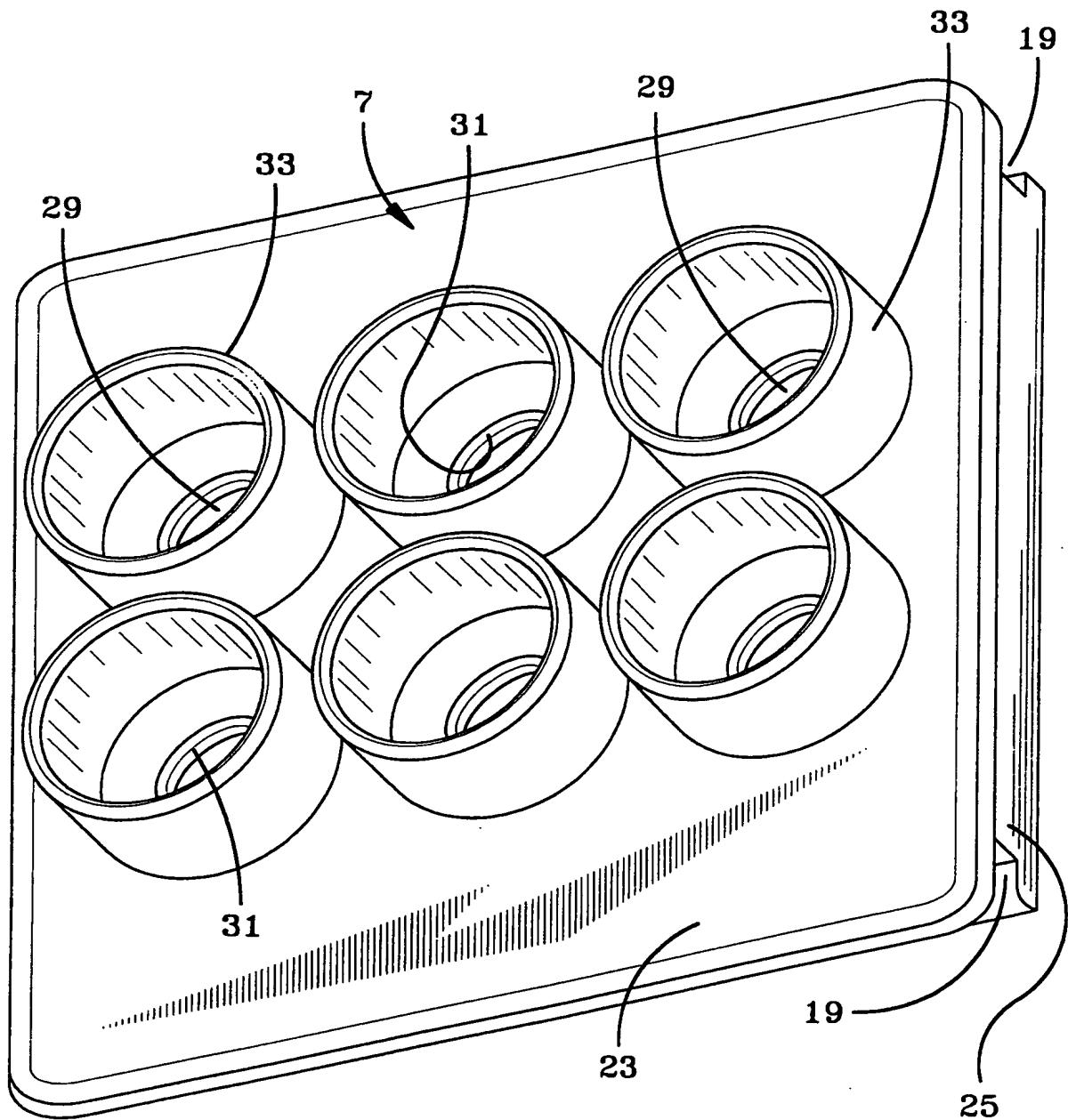


FIG-3

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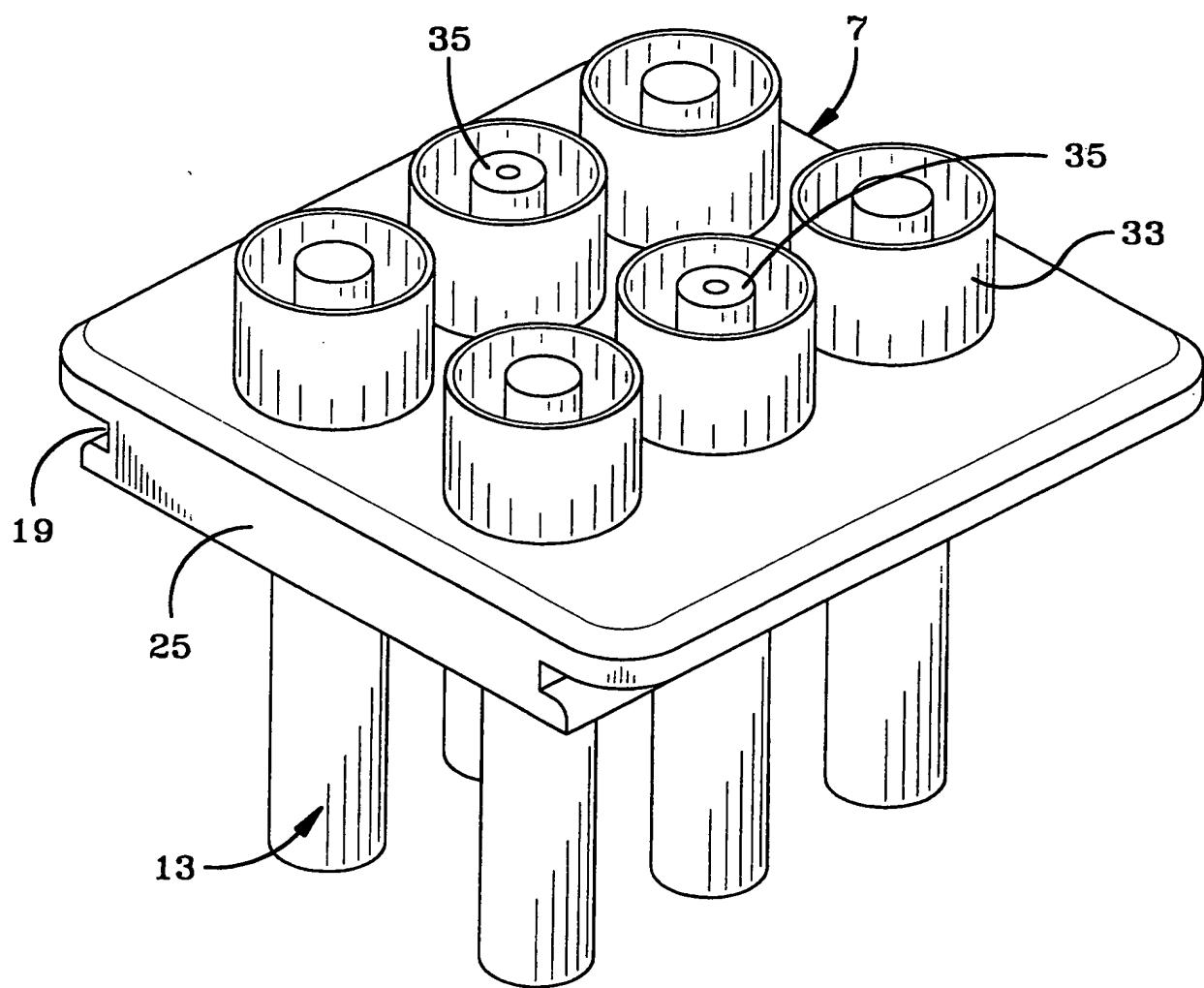


FIG-4

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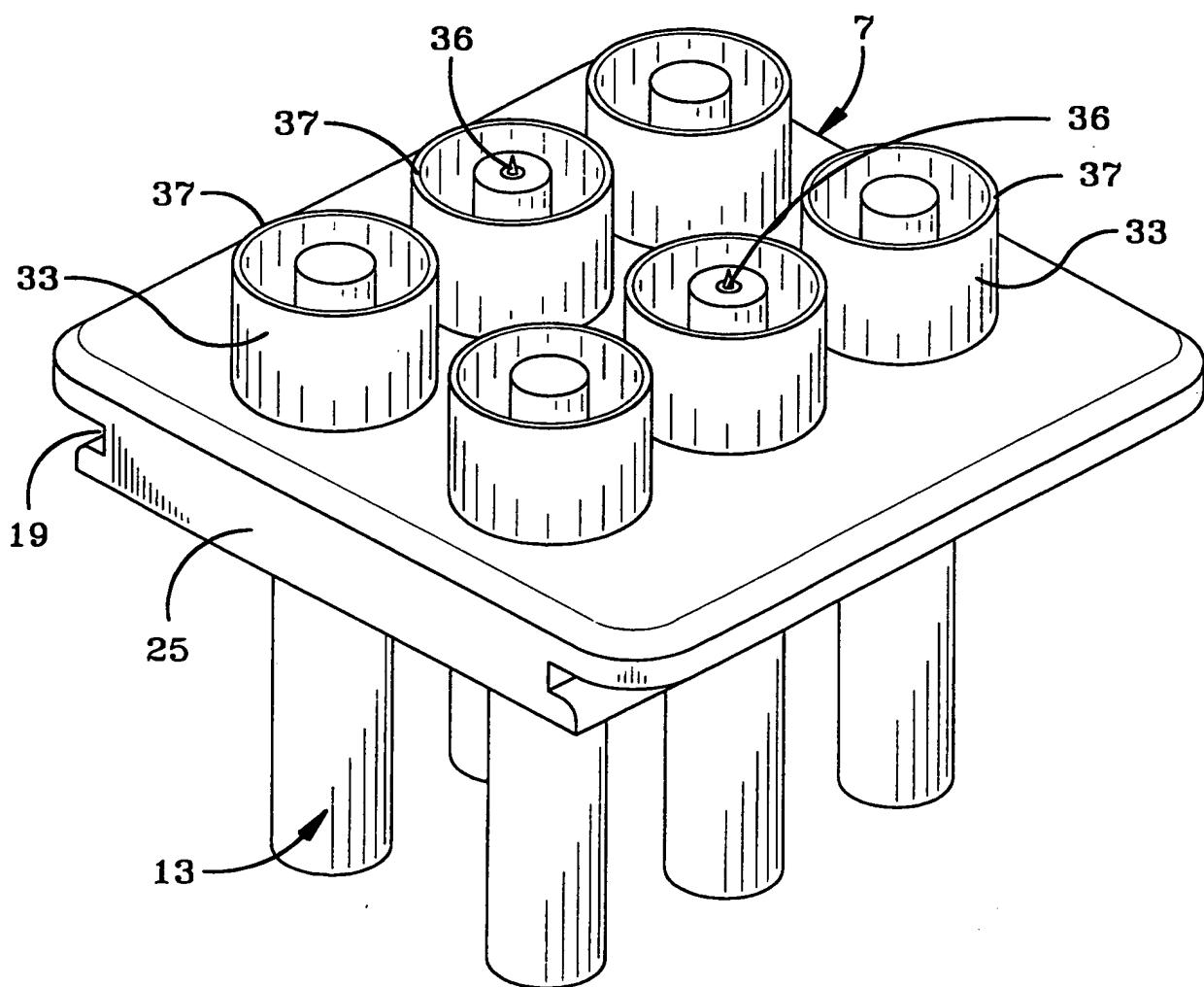
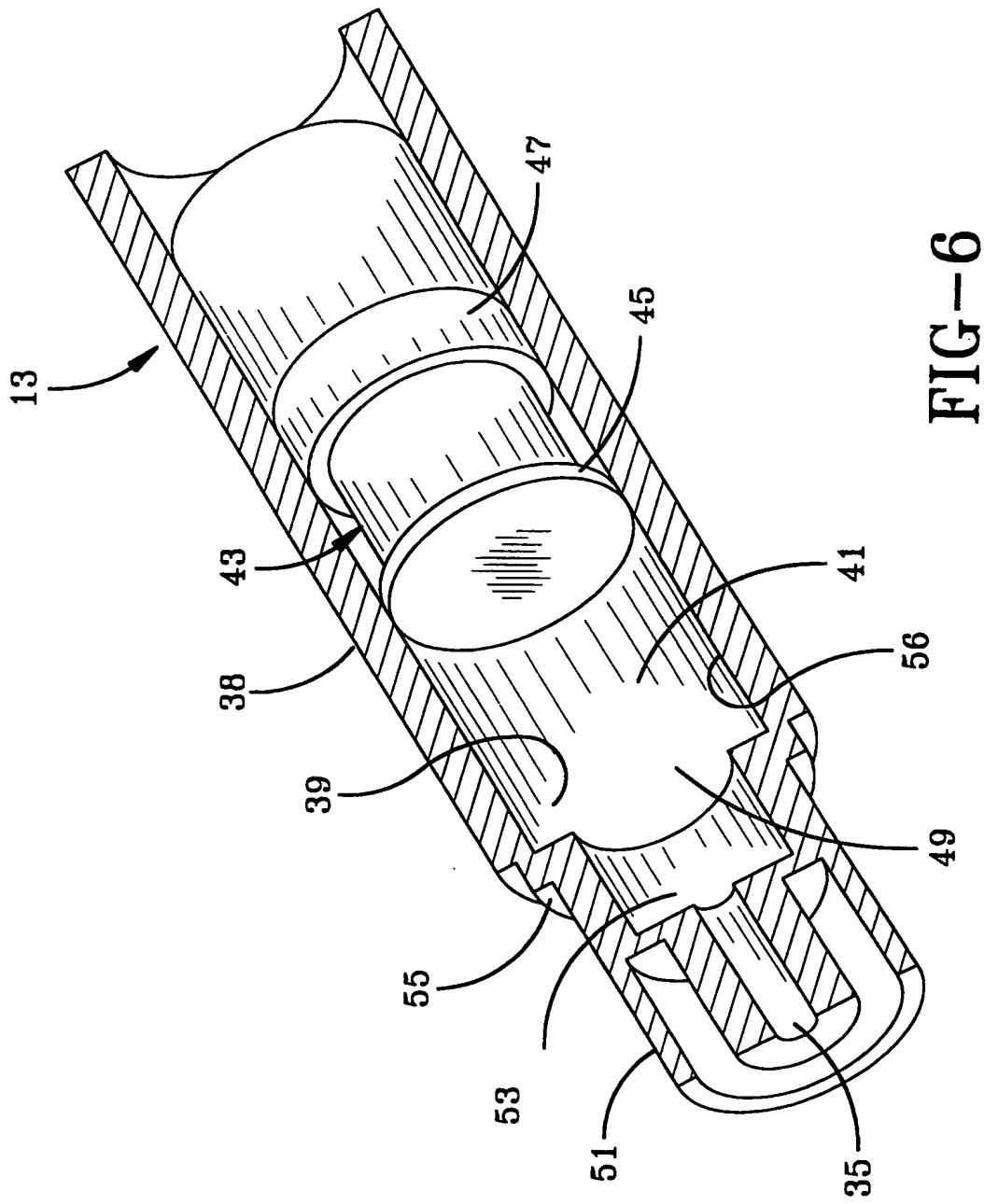


FIG-5

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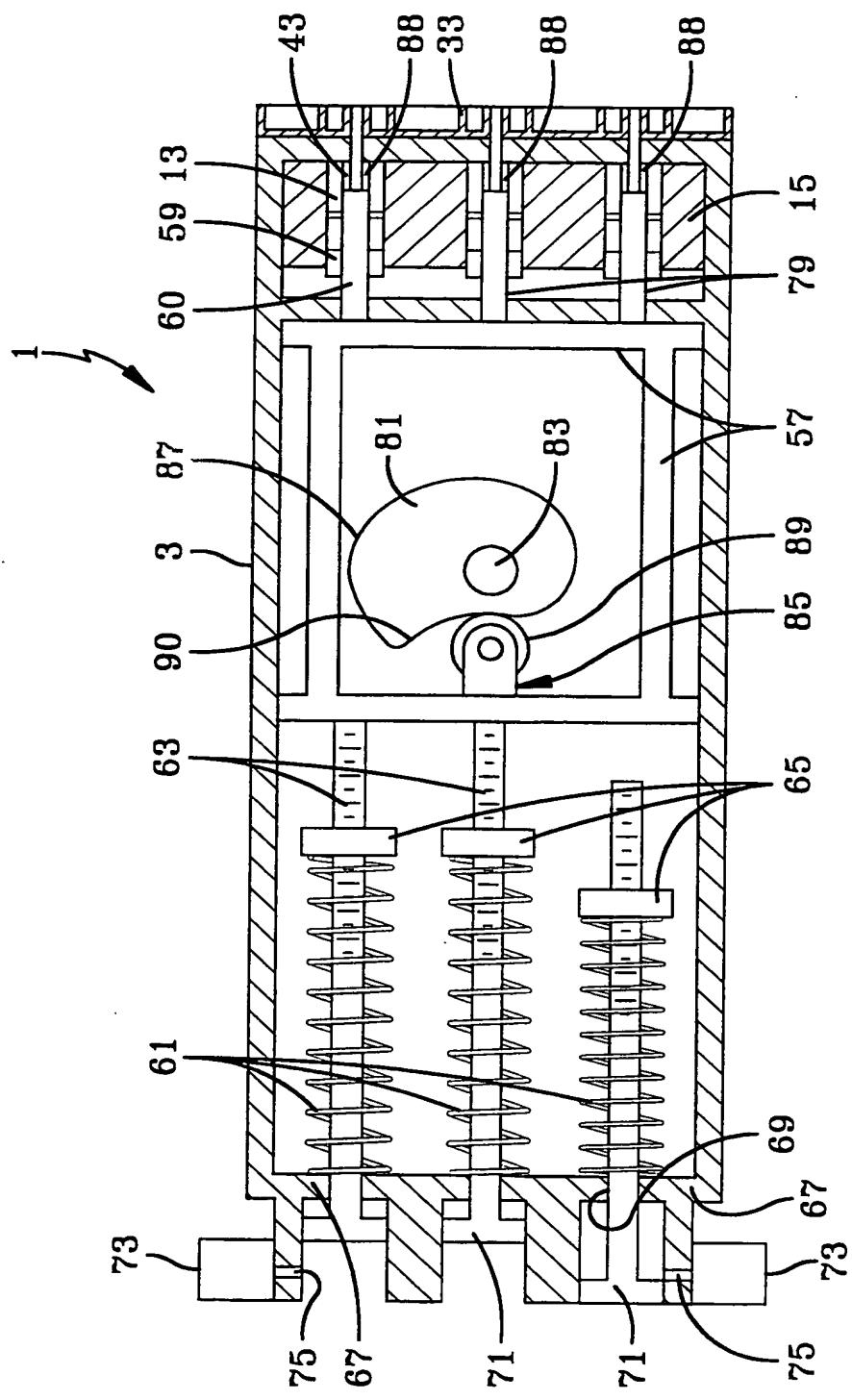


FIG-7

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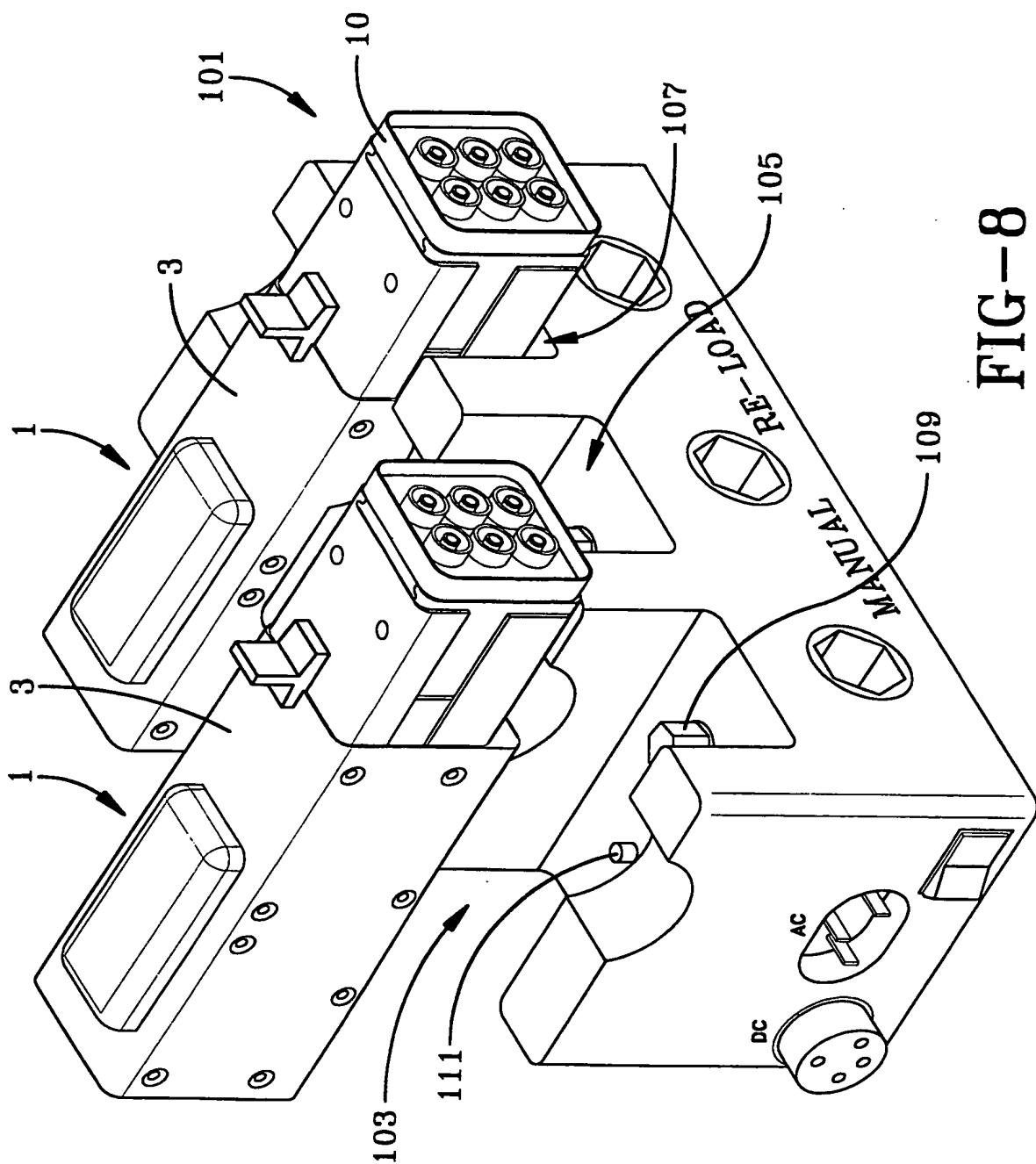
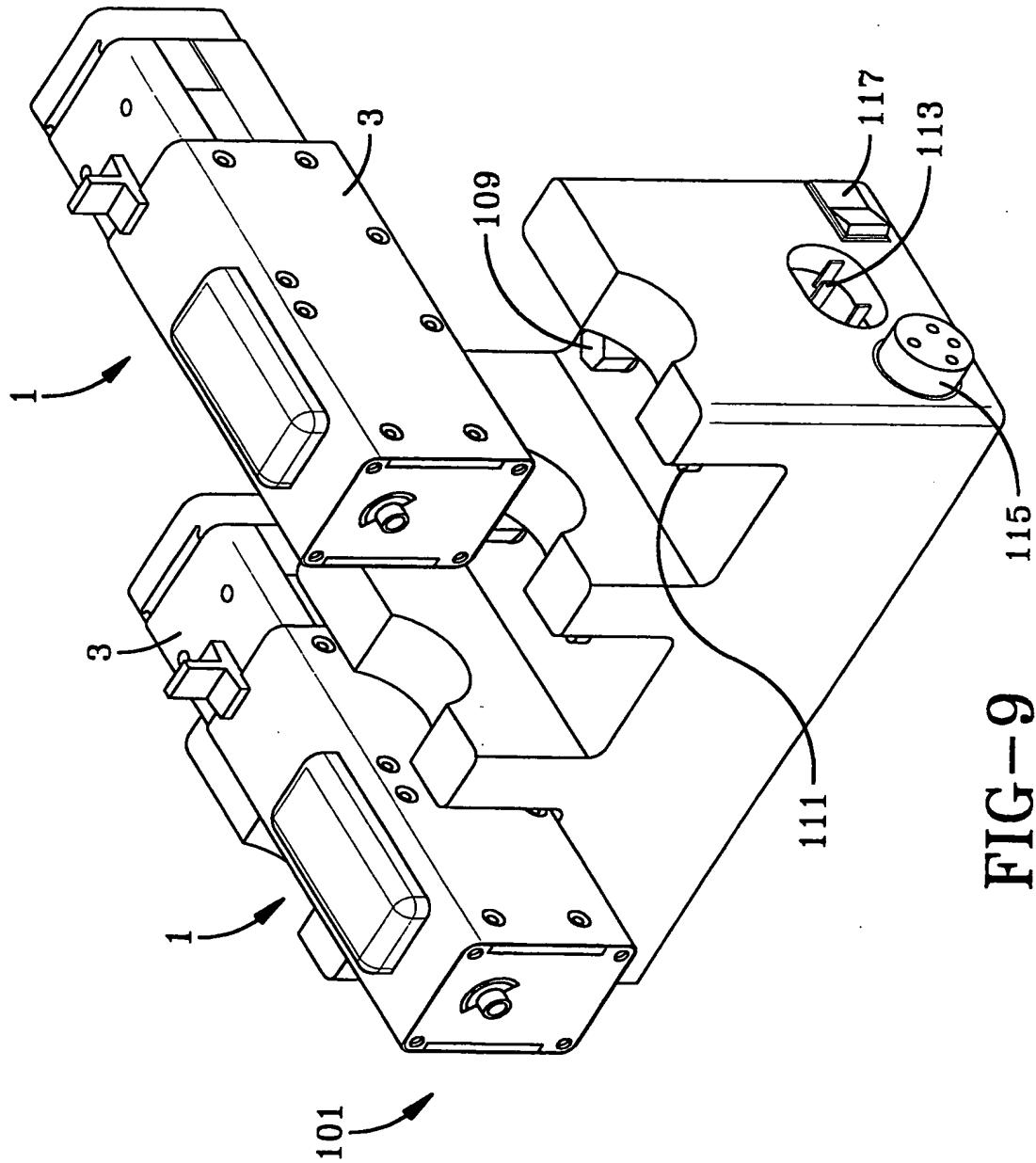


FIG-8

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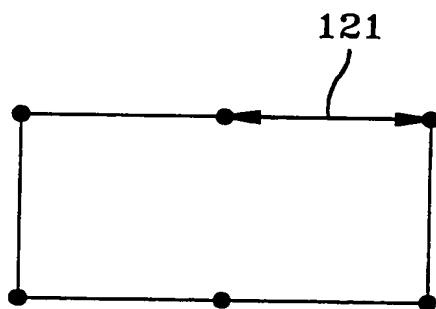


FIG-10

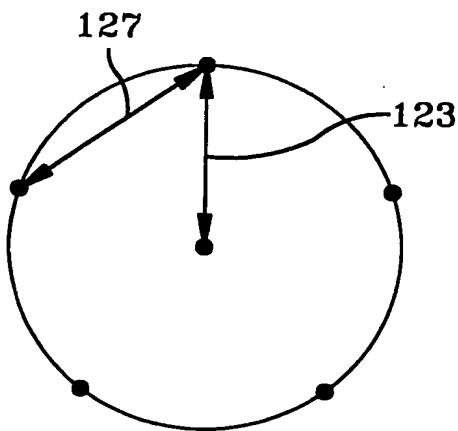


FIG-11

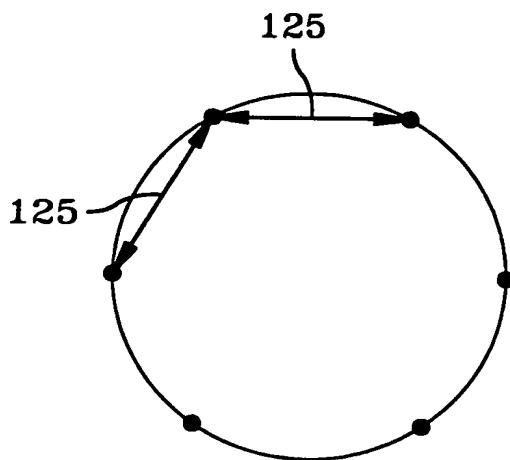


FIG-12

includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 11 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive 5 mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 10 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use 15 compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be 20 done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also 25 possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also 30 apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/07470

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 5/00, 24, 178, 315

US CL : 604/93.01, 183, 191, 200, 218, 232-234, 242, 243

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/93.01, 183, 191, 200, 218, 232, 233, 234, 242, 243

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,253,785 A (HABER et al.) 19 October 1993, col. 7 line 18, and col. 9 lines 35-40.	1-29
X, E	US 6,056,716 A (D'ANTONIO et al.) 02 May 2000, col. 14 lines 1 and 2.	23, 27, 28, 30
X	US 4,677,980 A (REILLY et al.) 07 July 1987, col. 5 lines 33-8, and col 6 line 63.	1, 23, 31-44, 46
X	US 4,089,334 A (SCHWEBEL et al.) 16 May 1978, col. 2 lines 59-66.	36, 44, 46
X	US 5,354,284 A (HABER et al.) 11 October 1994, col. 8 line 16.	36, 45
X	US 4,518,384 A (TARELLO et al.) 21 May 1985, col., 14 lines 27-32.	36, 47

 Further documents are listed in the continuation of Box C.  See patent family annex.

* A	Special categories of cited documents: document defining the general state of the art which is not considered to be of particular relevance	* T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* E	earlier document published on or after the international filing date	* X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* O	document referring to an oral disclosure, use, exhibition or other means	* &*	document member of the same patent family
* P	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search  
16 JUNE 2000Date of mailing of the international search report  
19 JUL 2000Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231Authorized officer   
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Facsimile No. (703) 305-3230

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference DA7119PCT (9)	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/07470	International filing date (day/month/year) 21 MARCH 2000	Priority date (day/month/year) 25 MARCH 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 5/00, 5/24 and US Cl.: 604/93.01, 183, 191, 200, 218, 232-234, 242, 243		
Applicant D'ANTONIO CONSULTANTS INTERNATIONAL, INC.		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>2</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>
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Date of submission of the demand 22 OCTOBER 2000	Date of completion of this report 20 MARCH 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Ann Lam <i>Diane Smith Jr.</i>
Facsimile No. (703) 305-3230	Telephone No. (703) 306-5560

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the claims:pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the drawings:pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_ the sequence listing part of the description:pages \_\_\_\_\_ (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.4.  The amendments have resulted in the cancellation of: the description, pages \_\_\_\_\_ NONE the claims, Nos. \_\_\_\_\_ NONE the drawings, sheets/fig \_\_\_\_\_ NONE5.  This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/07470

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO

**2. citations and explanations (Rule 70.7)**

Claims 1-47 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an injection system with a latching and release apparatus for latching a holding member to a housing, and for releasing said holding member and containers held by said holding member from said housing. The prior art also does not teach an injection system comprising at least two cartridges, and a ram apparatus having separate rams, each movable with respect to one of said cartridges. The prior art also does not teach a station comprising an energy transferring apparatus, and a re-energizing mechanism.

## ----- NEW CITATIONS -----

NONE

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-12, 14-15, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
Page 13, filed with the letter of 21 February 2001.

This report has been drawn on the basis of the claims,  
page(s) NONE, as originally filed.  
page(s) NONE, as amended under Article 19.  
page(s) NONE, filed with the demand.  
and additional amendments:  
Pages 16-23, filed with the letter of 21 February 2001.

This report has been drawn on the basis of the drawings,  
page(s) 1-10, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the sequence listing part of the description:  
page(s) NONE, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

## PATENT COOPERATION TREATY

DA 7/19/02

PCT

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

HOCHBERG, D., Peter  
D. Peter Hochberg Co., L.P.A.  
6th Floor  
1940 East Sixth Street  
Cleveland, OH 44114-2294  
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)  
28 September 2000 (28.09.00)

Applicant's or agent's file reference

## IMPORTANT NOTICE

International application No. PCT/US00/07470	International filing date (day/month/year) 21 March 2000 (21.03.00)	Priority date (day/month/year) 25 March 1999 (25.03.99)
---	--	--

Applicant

D'ANTONIO CONSULTANTS INTERNATIONAL, INC. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:  
AU,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:  
AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CN,CU,CZ,DE,DK,EA,EE,EP,ES,FI,GB,GD,GE,GH,  
GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,OA,  
PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZA,ZW  
The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 28 September 2000 (28.09.00) under No. WO 00/56381

## REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a **demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

## REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

J. Zahra

Telephone No. (41-22) 338.83.38

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

Date of mailing (day/month/year) 27 February 2001 (27.02.01)
Applicant's or agent's file reference DA7119 PCT
International application No. PCT/US00/07470

To:  HOCHBERG, D., Peter D. Peter Hochberg Co., L.P.A. 6th Floor 1940 East Sixth Street Cleveland, OH 44114-2294 ETATS-UNIS D'AMERIQUE
---

## IMPORTANT NOTIFICATION

International filing date (day/month/year)  
21 March 2000 (21.03.00)

## 1. The following indications appeared on record concerning:

the applicant     the inventor     the agent     the common representative

Name and Address D'ANTONIO, Nicholas, F. 7695 Fly Road Liverpool, NY United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

the person     the name     the address     the nationality     the residence

Name and Address D'ANTONIO, Nicholas, F. 5479 Lake Road Tull, NY 13159 United States of America	State of Nationality US	State of Residence US
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

## 3. Further observations, if necessary:

## 4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer  Simin Baharlou
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## ATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: D. PETER HOCHBERG  
D. PETER HOCHBERG CO., L.P.A.  
1940 E. 6TH STREET, 6TH FLOOR  
CLEVELAND, OHIO 44114-2294

PCT

WRITTEN OPINION

(PCT Rule 66)

RECEIVED  
U.S. POSTAL  
LAW OFFICES OF  
D. PETER HOCHBERG

		Date of Mailing (day/month/year)	22 DEC 2000
Applicant's or agent's file reference DA7119PCT (9)		REPLY DUE	within TWO months from the above date of mailing
International application No. PCT/US00/07470	International filing date (day/month/year) 21 MARCH 2000	Priority date (day/month/year) 25 MARCH 1999	
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61M 5/00, 24, 178, 315 and US CI.: 604/93.01, 183, 191, 200, 218, 232-234, 242, 243			
Applicant D'ANTONIO CONSULTANTS INTERNATIONAL, INC.			

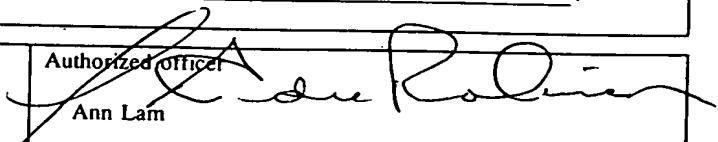
1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I  Basis of the opinion
  - II  Priority
  - III  Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
  - IV  Lack of unity of invention
  - V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI  Certain documents cited
  - VII  Certain defects in the international application
  - VIII  Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 25 JULY 2001

Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized Officer Ann Lam 
Facsimile No. (703) 305-3230	Telephone No. (703) 306-5560

## PATENTS

Resp. Due	2-22-01	
Appeal Due		
Stat. Appeal		
Issue Fee Due		
Reminder	1-22-01	
DJM	cll	DRS

## I. Basis of the opinion

## 1. With regard to the elements of the international application:\*

 the international application as originally filed the description:pages 1-15, as originally filed  
pages NONE  
pages NONE, filed with the demand the claims:pages 16-23, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of the drawings:pages 1-10, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of the sequence listing part of the description:pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
 the language of publication of the international application (under Rule 48.3(b)).  
 the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

contained in the international application in printed form.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority in written form.  
 furnished subsequently to this Authority in computer readable form.  
 The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
 The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

the description, pages NONE  
 the claims, Nos. NONE  
 the drawings, sheets/fig NONE

5.  This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. statement**

Novelty (N)	Claims <u>30</u>	YES
	Claims <u>1-29, and 31-47</u>	NO
Inventive Step (IS)	Claims <u>30</u>	YES
	Claims <u>1-29, and 31-47</u>	NO
Industrial Applicability (IA)	Claims <u>1-47</u>	YES
	Claims <u>NONE</u>	NO

**2. citations and explanations**

Claims 1-29 lack novelty under PCT Article 33(2) as being anticipated by Haber et al., US 5,253,785.

Claims 1, 23, 31-44, and 46 lack novelty under PCT Article 33(2) as being anticipated by Reilly et al., US, 4,677,980.

Claim 30 meets the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest an injection system having at least two injectate cartridges, each having a dispensing channel with an exit nozzle, and a plunger, a holding member, a ram means, a carriage, a spring means, a carriage resetting means, a releasable latching means, a housing having a spring mean, said spring mean moving said carriage, said spring means including movable rods, and a solenoid.

Claims 36, 44, and 46 lack novelty under PCT Article 33(2) as being anticipated by Schwebel et al., US 4,089,334.

Claims 36 and 45 lack novelty under PCT Article 33(2) as being anticipated by Haber et al., US 5,354,284.

Claims 36 and 47 lack novelty under PCT Article 33(2) as being anticipated by Tarello et al., 4,518,384.

**----- NEW CITATIONS -----**

NONE

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**TIME LIMIT:**

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

## PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

Date of mailing (day/month/year) 23 November 2000 (23.11.00)	To:  Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/US00/07470	Applicant's or agent's file reference
International filing date (day/month/year) 21 March 2000 (21.03.00)	Priority date (day/month/year) 25 March 1999 (25.03.99)
Applicant D'ANTONIO, Nicholas, F. et al	

1. The designated Office is hereby notified of its election made:

 in the demand filed with the International Preliminary Examining Authority on:

22 October 2000 (22.10.00)

 in a notice effecting later election filed with the International Bureau on:2. The election  was was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Diana Nissen  Telephone No.: (41-22) 338.83.38
---	--

PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only	
PCT/US 00/07470	
International Application No.	
21 MAR 2000 (21.05.00)	
International Filing Date	
PCT INTERNATIONAL	
APPLICATION FORM	
Name of receiving Office and "PCT International Application"	
Applicant's or agent's file reference (if desired) (12 characters maximum)	

## Box No. I TITLE OF INVENTION

HYPODERMIC INJECTION SYSTEM

## Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

D'Antonio Consultants International, Inc.  
6308 Fly Road  
East Syracuse, New York 13057 [U.S.A.]  
US

This person is also inventor.

Telephone No.  
(216) 771-3800

Faximile No.  
(216) 771-3804

Teleprinter No.

State (that is, country) of nationality:  
US

State (that is, country) of residence:  
US

This person is applicant  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

## Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

D'Antonio, Nicholas F.  
7695 Fly Road  
Liverpool, New York [U.S.A.]  
US

This person is:

applicant only

applicant and inventor

Inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:  
US

State (that is, country) of residence:  
US

This person is applicant  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

Further applicants and/or (further) inventors are indicated on a continuation sheet.

## Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:  agent  common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Hochberg, D. Peter  
D. Peter Hochberg Co., L.P.A.  
1940 E. 6th Street - 6th Floor  
Cleveland, Ohio 44114-2294 [U.S.A.]  
US

Telephone No.  
(216) 771-3800

Faximile No.  
(216) 771-3804

Teleprinter No.

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

TUS 00/07 470

Sheet No. 2

## Continuation of Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

If none of the following sub-boxes is used, this sheet should not be included in the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Wagner, John T.  
510 Wilde Avenue  
Drexel Hill, Pennsylvania 19026 [U.S.A.]  
US

This person is:

 applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant for the purposes of:  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Colvin, Richard O.  
1948 Connors Road  
Baldwinsville, New York 13027 [U.S.A.]  
US

This person is:

 applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant for the purposes of:  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

 applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

 applicant only applicant and inventor inventor only (If this check-box is marked, do not fill in below.)

State (that is, country) of nationality:

State (that is, country) of residence:

This person is applicant for the purposes of:  all designated States  all designated States except the United States of America  the United States of America only  the States indicated in the Supplemental Box

Further applicants and/or (further) inventors are indicated on another continuation sheet.

Form PCT/RO/101 (continuation sheet) (July 1998; reprint July 1999).

See Notes to the request form

(Request—International Application under the Patent Cooperation Treaty [13-2]—page 2 of 5)

Sheet No. 3

## Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

## Regional Patent

AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT

EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT

EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT

OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

<input checked="" type="checkbox"/> AE United Arab Emirates	<input checked="" type="checkbox"/> LR Liberia
<input checked="" type="checkbox"/> AL Albania	<input checked="" type="checkbox"/> LS Lesotho
<input checked="" type="checkbox"/> AM Armenia	<input checked="" type="checkbox"/> LT Lithuania
<input checked="" type="checkbox"/> AT Austria	<input checked="" type="checkbox"/> LU Luxembourg
<input checked="" type="checkbox"/> AU Australia	<input checked="" type="checkbox"/> LV Latvia
<input checked="" type="checkbox"/> AZ Azerbaijan	<input checked="" type="checkbox"/> MD Republic of Moldova
<input checked="" type="checkbox"/> BA Bosnia and Herzegovina	<input checked="" type="checkbox"/> MG Madagascar
<input checked="" type="checkbox"/> BB Barbados	<input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia
<input checked="" type="checkbox"/> BG Bulgaria	
<input checked="" type="checkbox"/> BR Brazil	<input checked="" type="checkbox"/> MN Mongolia
<input checked="" type="checkbox"/> BY Belarus	<input checked="" type="checkbox"/> MW Malawi
<input checked="" type="checkbox"/> CA Canada	<input checked="" type="checkbox"/> MX Mexico
<input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein	<input checked="" type="checkbox"/> NO Norway
<input checked="" type="checkbox"/> CN China	<input checked="" type="checkbox"/> NZ New Zealand
<input checked="" type="checkbox"/> CU Cuba	<input checked="" type="checkbox"/> PL Poland
<input checked="" type="checkbox"/> CZ Czech Republic	<input checked="" type="checkbox"/> PT Portugal
<input checked="" type="checkbox"/> DE Germany	<input checked="" type="checkbox"/> RO Romania
<input checked="" type="checkbox"/> DK Denmark	<input checked="" type="checkbox"/> RU Russian Federation
<input checked="" type="checkbox"/> EE Estonia	<input checked="" type="checkbox"/> SD Sudan
<input checked="" type="checkbox"/> ES Spain	<input checked="" type="checkbox"/> SE Sweden
<input checked="" type="checkbox"/> FI Finland	<input checked="" type="checkbox"/> SG Singapore
<input checked="" type="checkbox"/> GB United Kingdom	<input checked="" type="checkbox"/> SI Slovenia
<input checked="" type="checkbox"/> GD Grenada	<input checked="" type="checkbox"/> SK Slovakia
<input checked="" type="checkbox"/> GE Georgia	<input checked="" type="checkbox"/> SL Sierra Leone
<input checked="" type="checkbox"/> GH Ghana	<input checked="" type="checkbox"/> TJ Tajikistan
<input checked="" type="checkbox"/> GM Gambia	<input checked="" type="checkbox"/> TM Turkmenistan
<input checked="" type="checkbox"/> HR Croatia	<input checked="" type="checkbox"/> TR Turkey
<input checked="" type="checkbox"/> HU Hungary	<input checked="" type="checkbox"/> TT Trinidad and Tobago
<input checked="" type="checkbox"/> ID Indonesia	<input checked="" type="checkbox"/> UA Ukraine
<input checked="" type="checkbox"/> IL Israel	<input checked="" type="checkbox"/> UG Uganda
<input checked="" type="checkbox"/> IN India	<input checked="" type="checkbox"/> US United States of America
<input checked="" type="checkbox"/> IS Iceland	
<input checked="" type="checkbox"/> JP Japan	<input checked="" type="checkbox"/> UZ Uzbekistan
<input checked="" type="checkbox"/> KE Kenya	<input checked="" type="checkbox"/> VN Viet Nam
<input checked="" type="checkbox"/> KG Kyrgyzstan	<input checked="" type="checkbox"/> YU Yugoslavia
<input checked="" type="checkbox"/> KP Democratic People's Republic of Korea	<input checked="" type="checkbox"/> ZA South Africa
<input checked="" type="checkbox"/> KR Republic of Korea	<input checked="" type="checkbox"/> ZW Zimbabwe
<input checked="" type="checkbox"/> KZ Kazakhstan	
<input checked="" type="checkbox"/> LC Saint Lucia	
<input checked="" type="checkbox"/> LK Sri Lanka	

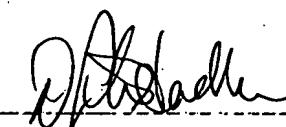
Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:


**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

PCT/US 00/07470

Sheet No. 4

Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:	national application: country	regional application: regional Office
international application: receiving Office				
item (1) 25 March 1994 (25.03.94) 25/03/1994	60/126,062	US		
item (2)				
item (3)				
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): <u>1</u> <small>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</small>				
Box No. VII INTERNATIONAL SEARCHING AUTHORITY				
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description (excluding sequence listing part) : 15	<input type="checkbox"/> separate signed power of attorney			
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includes a drive mechanism 109 having a hexagonal shape for engaging a corresponding portion of cam axle 83. An enable button 111 is preferably provided so that when a system 1 is inserted in a compartment 103, 105, 107, button 111 is depressed and drive mechanism 109 rotates cam 81 to its loaded or injection ready position. The drive 5 mechanism stops rotating upon the actuation of an internal disable switch which detects the correct amount of rotation. These injector positions could be sensed electronically rather than using the button switches as shown. The hand-held portion, system 1 of Figure 8, is then removed from station 101 for an injection to be made. The system is then reloaded and reset with loading station 101. While injection system 1 in Figure 8 10 has the same form (less the handle) as shown in Figure 1, in an actual commercial system, it will have a shape that is easily held by the user when giving an injection.

The rear portion of the apparatus shown in Figure 8 is shown in Figure 9. Loading station 101 can be energized using the AC input 113 or a DC input 115. An on/off switch 117 is also provided. The power can be an AC grid or battery, or can use 15 compressed gas, ignitable gas such as butane, hydraulic drive, or manual operation using a hand crank or a foot pedal. Systems 1 shown in Figures 8 and 9 can be easily moved when the injection procedures are completed. Load stations 101 need not be picked up by the health care worker when an injection is given. Loading station 101 and system 1 are only brought together when spring compression is needed, and this could even be 20 done using a long speedometer-type cable connection instead of a direct contact interface as shown in Figures 8 and 9. Even though Figures 8 and 9 show DC and AC power inputs, manual loading is also possible in case of power failure or lack of power at a particular location.

Although Figure 7 shows a spring for each cartridge, a single spring is also 25 possible. Other means for providing pressure for dispensing injectate from the holding members are possible. Other springs besides wire springs could be used as well, including resilient plastic springs, elastomeric springs such as rubber or rubber-like materials, and possibly electro-magnetic fields. Although the cam system shown in Figure 7 has been found to be effective, other means for setting the system would also 30 apply. For example, there could be gearing systems, linear systems, such as those with linear gears, pawl and gear mechanisms, belts, rollers, and the like could be employed.

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ADD B37  
We claim:

1. A hypodermic injection system comprising:  
a housing for housing at least one injectate container for an injectate to be injected from the system into a body;
- 5 a container-holding member for holding the respective injectate containers in position during the injection process for proper injection into the body; and  
latching and release apparatus for releasably latching said holding member to said housing during the injection process, and for releasing said holding member and the containers held by said holding member from said housing without any  
10 physical contact by the user, for non-contaminating disposal after the injection process.
2. A system according to claim 1 wherein said housing houses at least two injectate containers, and said disposable holding member is a structure having openings for holding each of the injectate containers.
3. A system according to claim 2 and further including guard walls around  
15 said openings for preventing splashing of the injectate or blood during an injection process.
4. A system according to claim 2 and further including splash guard walls around the outer edge of said container-holding member for preventing the splashing of the injectate during an injection process.
- 20 5. A system according to claim 2 wherein said openings are dimensioned to be press fit with the injectate containers to hold the containers in place.
6. A system according to claim 1 wherein said housing has a front portion, said holding member comprises a front plate, and said latching and release apparatus includes a groove in one of said front plate and said housing and a releasable latching  
25 member in the other of said front plate and said housing for releasably entering said groove to latch said front plate to said housing.
7. A system according to claim 2 and further comprising actuatable injectate release device for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, and a manually operable trigger  
30 device for actuating said injectate release device.
8. A system according to claim 7 wherein said injectate release device

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comprises energy storage apparatus for storing energy to be applied to the respective injectate containers, and wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

5 9. A system according to claim 7 wherein said energy storage apparatus comprises at least one spring, a latch for holding the spring in a set condition, and wherein said trigger device comprises a release trigger for releasing said latch to commence the injection process.

10 10. A system according to claim 1 wherein said locking and release apparatus comprises at least one locking member for cooperating with said container-holding member to lock said holding member to said housing, device for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and an ejection device for ejecting said holding member and the respective 15 containers held by said holding member from said housing.

11. A system according to claim 10 wherein said holding member is a plate with a peripheral edge having a groove, and wherein said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate.

20 12. A hypodermic injection system according to claim 1 and further including at least two injectate containers, said holding member holding said containers in proper position.

13. A system according to claim 12 wherein said injectate containers are disposable cartridges, said cartridges each including an injectate channel having injectate 25 nozzles, and wherein said holding member comprises cartridge holders for holding said cartridges for dispensing injectate through said respective channels during the injection process.

14. A system according to claim 13 wherein at least one of said cartridges are inactive cartridges having pseudo-channels which are constructed to appear as injectate 30 channels but are non-functional as channels, and said inactive cartridges have externally visible surfaces adjacent said pseudo-channels being coded to appear differently from  
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corresponding surfaces of the active cartridges.

15. A system according to claim 12 wherein said injectate containers are disposable injectate cartridges, and wherein said holding member comprises cartridge-holding surfaces for holding said cartridges in position to dispense injectate, said 5 injectate cartridges comprising:

an outer wall having an inner wall surface defining an inner chamber;

a plunger engaging said inner wall surface and being movable in said chamber, said plunger defining an injectate-holding portion of said chamber and said chamber having an injectate dispensing end having an exit nozzle, said dispensing end 10 being configured to engage the respective cartridge-holding surfaces, said plunger being drivable into said injectate-holding portion to dispense the injectate through said respective nozzles from said respective cartridges during the injection process.

16. A system according to claim 15 wherein said injectate-holding portion of at least one of said cartridges comprising a rupturable seal dividing said holding portion 15 into two compartments, one of said compartments holding a lyophilized part of an injectate and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate.

17. A system according to claim 16 and further including a device for rupturing said seal.

20 18. A system according to claim 1 and further including a biasing device for placing sufficient pressure on said respective containers to force the injectate out of the containers at jet velocity.

19. A system according to claim 12 wherein said injectate containers are six cartridges having injectate exits, said exits being disposed in a rectangular order having 25 three pairs of opposing exits.

20. A system according to claim 12 wherein said injectate containers are cartridges having perforators for piercing the skin of a body and through which injectate flows during an injection process.

21. A system according to claim 1 wherein said housing houses an injectate 30 container, and said disposable holding member is a structure having openings for holding said injectate container.

22. A system according to claim 21 and further including a guard wall around said opening for preventing splashing of the injectate or blood during an injection process.

23. A hypodermic injection system for dispensing injectate, said system comprising: from at least two injectate cartridges, each of said cartridges having a dispensing channel with an exit nozzle, and a plunger for moving through each of the cartridges to dispense injectate from each of the cartridges;

10 a holding member for holding said respective injectate cartridges with said dispensing channels directed in a common direction;

15 a ram apparatus having separate rams, each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle;

20 a carriage movable from a set position to a dispensing position for moving said ram apparatus at uniform pressures during an injection process;

24. A system according to claim 23 and further including a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said latching device, said carriage resetting apparatus and said releasable latching device.

25 25. A system according to claim 24 and further comprising:

26. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam configured for moving said cam follower and said carriage from the dispensing position to the set position.

27. A system according to claim 23 and further including a housing having a fixed wall for said spring apparatus, and wherein said spring apparatus comprises at least one spring having one end engaged with said fixed wall, and the other end movable to the cocked position when said carriage moves to the set position, said set of springs 5 moving said carriage from the set position to the dispensing position in response to release of said latching device.

28. A system according to claim 27 wherein said spring apparatus further includes movable rods associated with the respective springs for guiding and positioning said springs, said rods having a wall for engaging the other end of the respective springs 10 and being movable in response to movement of said carriage from the dispensing position to the set position for moving said respective springs to the cocked position and wherein said latching device comprises a first latching member extending from said housing and a second latching member on said rods, said first and second latching members having one condition for holding said rods and said respective springs in the 15 cocked position and a second condition for releasing said rods and said respective springs. said respective springs then moving said carriage assembly to the dispensing position.

29. A system according to claim 23 wherein said carriage resetting apparatus comprises a cam follower operatively connected to said carriage and a cam movable 20 from an initial position to a final position and configured for moving said cam follower to move said carriage from the dispensing position to the set position, and a trigger for moving said cam from the final position to the initial position and for releasing said latching device to release said latching device to effect the movement of said spring apparatus from the cocked position to move said carriage from the set position to the 25 dispensing position.

30. A system according to claim 28 and further including a solenoid responsive to sensing signals for releasing said first latching member to unlatch said spring apparatus.

31. A system according to claim 23 wherein said carriage resetting apparatus 30 is operable for moving said carriage from the dispensing position to the set position, and a drive apparatus movable for operating said resetting apparatus, said drive apparatus

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being configured to be moved by a correspondingly configured motor driven device.

32. A system according to claim 31 wherein said carriage resetting apparatus is a cam follower for moving said carriage from the dispensing position to the set position, and said drive apparatus is a cam operatively connected to said cam follower, 5 said cam being rotatable by a motor and configured to move said cam follower and said carriage from the dispensing condition to the set position, and said latching device latching said spring apparatus in the cocked position in response to movement of said carriage to the set position.

33. A system according to claim 31 and further including:

10 a housing for housing said holding member, said ram apparatus, said carriage assembly, said spring apparatus, said carriage assembly resetting apparatus, said drive apparatus and said releasable latching device; and

15 said system further comprising a handle attached to said housing. said handle including:

15 a motor;

20 a movable tool driven by said motor for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position; and

25 a power input apparatus for supplying electric power to said motor.

34. A system according to claim 31 and further including:

20 a housing for housing said holding member, said ram apparatus, said carriage, said spring apparatus, said carriage resetting apparatus. said drive apparatus and said releasable latching device; and

25 a loading station for cooperating with said housing to operate said carriage resetting apparatus, said loading station including a motor and a movable tool for engaging said drive apparatus to operate said carriage resetting apparatus for moving said carriage from the dispensing position to the set position.

35. A system according to claim 23 and further including a sensing apparatus for emitting a sensing signal to indicate the presence or absence of at least one cartridge 30 held by said holding member, and wherein said releasable latching device operates in response to the presence or absence of the sensing signal.

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36. A station for re-energizing a hypodermic injection system, the injection system having a mechanical energy storing apparatus for releasing stored energy when the system makes an injection, the mechanical energy storing apparatus having an input mechanism for cooperating with a re-energizing mechanism, said station comprising:

5 an energy transferring apparatus for transferring energy from an energy source;

10 a re-energizing mechanism for transmitting energy from said energy transferring apparatus to the input mechanism of the energy storing apparatus, said re-energizing mechanism cooperating with the input mechanism to effect the transmission of energy from said energy transferring apparatus to the mechanical energy storing apparatus.

15 37. A station according to claim 1 wherein the injection system has a predetermined external configuration and the input mechanism has a drivable surface for receiving energy to be stored in the energy storing apparatus, and wherein said re-energizing apparatus has a drive surface for cooperating with the drivable surface to re-energize the energy storing apparatus of the injection system.

20 38. A station according to claim 37 wherein the input mechanism comprises a cam mounted on an axle and the drivable surface is a surface of the axle, and wherein said drive surface of said re-energizing apparatus is a device for contacting the drivable surface and rotating the axle to rotate the cam.

25 39. A station according to claim 37 wherein the injection system has a predetermined external configuration, and said station includes at least one nesting apparatus for receiving and supporting the injection system, and wherein said drive surface cooperates with the drivable surface of the injection system to re-energize the energy storing apparatus of the system.

40. A system according to claim 39 wherein the energy storing apparatus of the injection system is at least one spring, and said re-energizing mechanism cocks the spring.

41. A station according to claim 40 wherein the injection system further includes a rotatable cam for operating a device to cock the spring and the drivable surface is connected to the cam, and wherein said drive surface cooperates with the

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drivable surface to rotate the cam and cock the spring.

42. A station according to claim 39 wherein the injection system includes apparatus for receiving disposable cartridges holding injectate, and wherein said station further including a supporting device to hold the injection system for reloading the 5 injection system with fresh cartridges containing injectate.

43. A station according to claim 36 wherein said re-energizing mechanism includes a manually operable member for transmitting energy from a person operating said member to the mechanical energy storing apparatus.

44. A station according to claim 36 wherein said re-energizing mechanism 10 includes a compressed gas operable member for transmitting energy from the compressed gas to the mechanical energy storing apparatus.

45. A station according to claim 36 wherein said re-energizing mechanism includes an hydraulically operable member for transmitting energy from the device exerting pressure on the hydraulic fluid to the mechanical energy storing apparatus.

15 46. A station according to claim 36 wherein said re-energizing mechanism includes an ignitable gas operable member for transmitting the ignition energy to the mechanical energy storing apparatus.

47. A station according to claim 36 wherein said re-energizing mechanism includes an electrically operable member for transmitting electrical energy to the 20 mechanical energy storing apparatus.

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